PROCESS AND ANALYTICAL VALIDATION WORKING GROUP

Purpose of Guidance

- To expand the use of current and future process analytical technology for controlling of both batch and continuous production of existing and new products

General Guidance Validation Issues

- Requirements for accepting PAT for conventional testing. What correlation is needed?
- Utilization of PAT in current processes
- PAT as “Alert” in the use of old technology. Out of trend vs. OOS

General Guidance Validation Issues (continued)

- PAT online can replace conventional testing. Identify filing requirement
- PAT end point can replace traditional end point (i.e.time)
- If sensors indicate improved process control, existing technology is accepted to meet current quality for release

General Guidance Validation Issues (continued)

- How to allow for improvement?
  - Rapid Review
  - Self Assessing
- New technology can not delay time to market. (vs. 3 batches)

General Guidance Validation Issues (continued)

- Dual development – fast to market with conventional testing
  - How to switch over when database is ready (file both initially? SUPAC?)
- cGMPs allow process improvement

General Guidance Validation Issues (continued)

- Update of method / algorithm model more frequent than conventional
- Reference methods validation guidances including ICH

General Guidance Validation Issues (continued)

- Validation of continuous process
  - Definition of batch size and impact of OOS
- Integration of unit operations into bigger steps
- How process set points are treated in feedback loops

General Guidance Validation Issues (continued)

- Validate appropriate parameters
- Chemometrics / data treatment